



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,930	03/17/2005	Shou Takashima	P25687	2173

7055 7590 10/18/2007
GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER

RAGHU, GANAPATHIRAM

ART UNIT	PAPER NUMBER
----------	--------------

1652

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

10/18/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No. 10/501,930	Applicant(s) TAKASHIMA ET AL.
	Examiner Ganapathirama Raghu	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8, 15 and 31-34 is/are pending in the application.
- 4a) Of the above claim(s) 31-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Application Status

In response to the Office Action mailed on 02/23/2007, applicants' filed a response on 06/18/2007. Said response, amended claims 8 and 15, canceled claims 1-2, 9, 10 and 16-30 and added new claims 31-34. Thus claims 8, 15 and 31-34 are pending in this application. Newly submitted claims 31-34 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 31-34 are directed to the method of use of the polypeptide in different processes. Inventions in claims 31-34 are drawn to methods and are patentably distinct. Each of the methods or processes has different steps, using different components and modes of operation with different end results. They do not require each other for practice; have separate utilities. For example, a method of selectively incorporating sialic acid into O-glycans in claim 31 or method of treatment of a hereditary disease in claim 32 or method to suppress cancer metastasis in claim 33 or method to study the influence of a physiological activity in claim 34 involve different and distinct steps and modes of operation, different kinds of preparation and mode of use and is subject to separate manufacture and sale.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Thus claims 8 and 15 are under consideration in the instant Office-action.

Objections and rejections not reiterated from previous action are hereby withdrawn.

Withdrawn-Claim Rejections: 35 USC § 112

Previous rejections of claims 1 and 10 rejected under 35 U.S.C. 112, first paragraph, for enablement and written description are withdrawn in view of cancellation of said claims.

Withdrawn -Claim Rejections 35 USC § 102

Previous rejections of claims 2, 8-9 and 15 rejected under 35 U.S.C. 102(a) as being anticipated by Takashima et al., (JBC., 2002, Vol. 277 (27): 24030-24038, on line publication April 29, 2002) are withdrawn in view of cancellation of claims 2 and 9 and amendments to claims 8 and 15.

Withdrawn -Claim Rejections 35 USC § 102

Previous rejections of claims 1-2 and 9-10 rejected under 35 U.S.C. 102(a) as being anticipated by Takashima et al., (JBC., 2002, Vol. 277 (27): 24030-24038, on line publication April 29, 2002) are withdrawn in view of cancellation of claims 1-2 and 9.

Maintained -Claim Rejections 35 USC § 103

Pervious rejection of claims 8 and 15 rejected under 35 U.S.C. 103(a) as being obvious over Kawai et al., (Nature 2001, Vol. 409: 685-690) are maintained. The rejection is explained in the previous Office Action.

In support of their request that the prior rejection of claims 8 and 15 under 35 U.S.C. 103(a) be withdrawn, applicants', provide the following argument.

(A) Kawai et al., do not provide any additional teaching concerning the substrate specificity of the predicted polypeptide nor does the reference suggest to culture *in vitro* isolated host cell transformed with an expression vector comprising a gene encoding a protein comprising amino acids 26 to 398 of the amino acid sequence of SEQ ID NO: 1.

The argument is not found to be persuasive for the following reasons.

(A) Reply: Claims 8 and 15 as written are directed only to a method of producing a polypeptide encoded by a polynucleotide comprising the nucleotides nucleotide residues 77-1270 of SEQ ID NO: 2 and encoding a polypeptide comprising the amino residues of 26-398 of SEQ ID NO: 1, and having O-glycan α 2,8-sialyltransferase activity, a recombinant expression vector comprising the gene encoding the said polypeptide and a host cell. The claims do not include any limitation regarding the substrate specificity of said polypeptide and therefore the obviousness analysis provided in the previous rejection (as stated on record in the Office Action mailed on 02/23/2007) to express the polypeptide of the instant invention by recombinant methods in isolated *in vitro* cells is maintained. Furthermore the substrate specificity of the enzyme is an inherent feature of the protein and the previous rejection the reasons for expressing the protein of interest.

Summary of Pending Issues

The following is a summary of issues pending in the instant application.

- 1) Amended claims 8 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over Kawai et al., (Nature 2001, Vol. 409: 685-690).
- 2) Newly added claims 31-34 are withdrawn as they are drawn to non-elected inventions.

Conclusion

None of the claims are allowable. Claims 8 and 15 are rejected for the reasons identified in the Rejections and Summary sections of this Office Action. Applicants must respond to the objections/rejections in each of the sections in this Office Action to be fully responsive for prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for

Art Unit: 1652

After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.

Patent Examiner

Art Unit 1652

Oct. 05, 2007.

/Rebecca Prouty/

Primary Examiner

Art Unit 1652